

JAN 14 1999

Date of Approval:

## FREEDOM OF INFORMATION SUMMARY

### ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-060

DECCOX®-M (decoquinate) Medicated Powder for Whole Milk

“... for the prevention of **coccidiosis** in ruminating and non-ruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*.”

Sponsored by

ALPHARMA INC.

NADA 141-060

FOIS 1

**I. GENERAL INFORMATION**

NADA Number: 141-060

Sponsor: Alpharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Established Name: decoquinate

Trade Name: DECCOX®-M (decoquinate) Medicated Powder for Whole Milk

Marketing Status: over-the-counter

Effect of NADA: This original NADA provides for the use of DECCOX®-M in whole milk fed to ruminating and nonruminating calves, including veal calves, for the prevention of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

**11. INDICATIONS FOR USE**

DECCOX®-M is indicated for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in ruminating and non-ruminating calves, including veal calves.

**III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE**

A. Dosage Form: medicated powder containing 0.8% decoquinate.

B. Route of Administration: orally, via whole milk

C. Approved Dose: DECCOX®-M is to be added to whole milk at a rate to provide 22.7 mg decoquinate per 100 pounds of body weight daily (0.5 mg decoquinate per kg body weight) for at least 28 days during periods of exposure to coccidiosis or when experience indicates that coccidiosis is likely to be a hazard.

**IV. EFFECTIVENESS**

Data supporting the effectiveness of decoquinate for the prevention of coccidiosis in ruminating calves and cattle are summarized in the FOI SUMMARY for NADA 39-417 for DECCOX® Coccidiostat Type A Medicated Article (41 FR 53003; December 3, 1976). Data to support effectiveness in non-ruminating calves was included in a supplement to this NADA (56 FR 15498, April 17, 1991). Data to support the addition of veal calves to the label was presented in a separate supplement approved in April 1992.

This original NADA provides for use of decoquinate in the same classes of cattle and conditions of use in a different formulation (whole milk vs Type C feeds, including milk replacers) and does not require additional effectiveness data.

## V. ANIMAL SAFETY

Data supporting the target animal safety of decoquinate for the prevention of **coccidiosis** in ruminating calves and cattle are summarized in the FOI SUMMARY for NADA 39-417 for DECCOX® Coccidiostat Type A Medicated Article (41 FR 53003; December 3, 1976). Data to support target animal safety in non-ruminating calves was included in a supplement to this NADA (56 FR: 15498, April 17, 1991). Data to support the addition of veal calves to the label was presented in a separate supplement approved in April 1992.

This original NADA provides for use of decoquinate in the same classes of cattle and conditions of use in a different formulation (whole milk vs Type C feeds, including milk replacers) and does not require additional target animal safety data.

## VI. HUMAN SAFETY

Data supporting the human food safety of DECCOX® Coccidiostat Type A Medicated Article are summarized in the FOI SUMMARY for NADA 39-417 (41 FR 53003; December 3, 1976).

Residue data to support the approval of decoquinate in non-ruminating calves was included in the supplemental approval for NADA 039-417, dated April 12, 1991 (56 FR 15498; April 12, 1991). Residue levels and the withdrawal time are not expected to be different when using DECCOX® in whole milk rather than in a milk replacer-based formulation.

Tolerances values for **decoquinate** of 1 ppm for skeletal muscle and 2 ppm for other tissues of chickens, cattle, and goats are established under 21 CFR 556.170.

Decoquinate is approved for cattle and calves at 22.7 mg/lb body weight/day (0.5 mg/kg) for at least 28 days in the feed and whole milk. No withdrawal period is required.

As part of the approval of this supplement, the Agency has taken the opportunity to update the human food safety information on this product and to **codify** an Acceptable Daily Intake (ADI) of 75 mcg/kg body weight/day under 21 CFR 556. This value is derived from the no observable effect level (NOEL) of 15 mg/kg body weight/day in a 12-week **subchronic** dog study and a safety factor of 200. The ADI is consistent with previous toxicity data submitted under NADA 39-417 and the conclusions of the summary report of the Committee for Veterinary Medicinal Products (CVMP) of the European Agency for the Evaluation of Medicinal Products.

## VII. AGENCY CONCLUSIONS

The existing data in NADA 141-060 satisfy the requirements of Section 512 of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. Decoquinatate when administered daily for at least 28 days in whole milk and fed at the rate of 22.7 mg/lb body weight (0.5 mg/kg) to ruminating and non-ruminating calves is safe and effective for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

As described in Section VI, the tolerance for residues of decoquinatate is codified as 1 ppm in skeletal muscle of cattle and as 2 ppm in other edible tissues and the ADI is codified at 75 mcg/kg body weight/day under 21 CFR 556.170. Decoquinatate is approved for use in calves and cattle at 22.7 mg/lb body weight/day (0.5 mg/kg) for at least 28 days with no withdrawal period required.

Adequate directions have been written for the layman and the conditions for mixing and use prescribed on the labeling are likely to be followed by the producer in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product can be approved with over-the-counter marketing status.

In accordance with 21 CFR 25.33(a)(3), this action qualifies for a categorical exclusion from the requirement to prepare an environmental assessment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(ii) of the FFDCFA, this approval for food-producing animals does not qualify for marketing exclusivity because the application does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

DECCOX®-M is not under any unexpired U.S. patents.

## VIII. APPROVED LABELING

Facsimile labeling components are attached for the 5-, 10-, and 50-pound bags.

VALLEYVIEW, ILL. (7)



# Deccox-M

Manufactured By  
**ALPHA PHARMA**  
1000 W. 10th St.  
Overland Park, KS  
Phone: 913-641-1000  
Fax: 913-641-1001



Bag size: 7" x 3" x 6"

## Decoquinat Medicated Powder for Whole Milk

To be added to whole milk for the prevention of coccidiosis in ruminating and non-ruminating calves, including veal calves caused by *Eimeria bovis* and *E. zuernii*

Feed for at least 28 days during periods of coccidiosis exposure or when experience indicates that coccidiosis is likely to be a hazard

Active ingredient Decoquinat ..... (3632 mg/lb) 0.8%

Inactive ingredients Lactose ..... 87%  
Other (corn meal, soybean 011, lecithin and silicon dioxide) ..... 12.2%

**Directions for use** Dosage:  
Feed at the rate of 22.7 mg per 100 lb body weight daily for at least 28 days or 0.5 mg per kg body weight daily for at least 28 days

### Mixing Directions - Individual Animal

Prepare fresh daily as shown below.  
¾ teaspoon per 60 lb body weight  
1 teaspoon per 120 lb body weight  
1½ teaspoons per 180 lb body weight

One level measuring teaspoon contains 28 mg of decoquinat

### Important

Completely stir daily dose of decoquinat powder into whole milk.  
Feed entire portion immediately.

### Mixing Directions - Continuous Agitation

Mix Deccox-M into the total amount of whole milk (0.5 to 1.5 gallon per calf daily) needed for the number of calves to be fed, using level measuring cups, teaspoons (tsp) or tablespoons (TBS), as shown below.  
Prepare fresh daily.

If Average Calf Weight (lbs) is:	5 Calves	10 Calves	20 Calves	40 Calves	80 Calves
75	1 TBS	2 TBS	¼ cup	½ cup	1 cup
100	4 tsp	8 tsp	⅓ cup	⅔ cup	1 ⅓ cups
150	2 TBS	¼ cup	½ cup	1 cup	2 cups
200	8 tsp	⅓ cup	⅔ cup	1 ⅓ cups	2 ⅔ cups

Feed each calf an equal portion of the total amount of medicated whole milk prepared as above.

### Important:

Stir or agitate continuously.  
Feed immediately in containers for individual animals only.  
Do not use in bulk feeding containers (i.e., Calf-Bars).

Failure to properly mix and feed this product may result in underdosing or overdosing of some animals due to settling out of the drug.

For Animal Use Only. Not for Use in Humans.  
Restricted Drug (CA). Use only as directed.

NADA 141-060, Approved by FDA.



Marketed by  
**ALPHARMA**  
Alpharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Net wt 5 LB (2.27 kg)

AHM-068 9807



**Deccox-M**  
 Medicated Powder for Horses  
 Deccox-M  
 Medicated Powder for Horses

**Deccox-M**  
 Medicated Powder for Horses

**Active Ingredient:** Deccox-M 1.2%  
**Other Ingredients:** 1.2%  
**Directions for Use:** See label for complete directions.

**Warnings:** Do not use in horses with known hypersensitivity to any of the ingredients. Do not use in horses with known hypersensitivity to any of the ingredients.

**Caution:** Do not use in horses with known hypersensitivity to any of the ingredients. Do not use in horses with known hypersensitivity to any of the ingredients.

**How to Use:** See label for complete directions.

**Net Wt 10 LB (4.53 kg)**



Bag Size 2 x 3" x 6"

ALPHARMA

Deccox-M

Deccox-M

Deccox-M

Net Wt 10 LB (4.53 kg)

ALPHARMA



ALPHARMA

Deccox-M

Deccox-M

## Decoquate Medicated Powder for Whole Milk

To be added to whole milk for the prevention of **coccidiosis** in  
ruminating and non-ruminating calves, including veal calves  
caused by *Eimeria bovis* and *E. zuernii*

Feed for at least 28 days during periods of **coccidiosis** exposure or  
when experience indicates that **coccidiosis** is likely to be a hazard

Active ingredient Decoquate ..... (3632mg/lb) 0.8%

Inactive ingredients Lactose ..... 87%  
Other (corn meal, soybean oil, lecithin and silicon dioxide) ..... 12.2%

### Directions for use Dosage:

Feed at the rate of 22.7mg per 100 lb body weight daily for at least  
28 days or 0.5 mg per kg body weight daily for at least 28 days.

#### Mixing Directions - Individual Animal

Prepare fresh daily as shown below.

½ teaspoon per 60 lb body weight  
1 teaspoon per 120 lb body weight  
1 ½ teaspoons per 180 lb body weight

One level measuring teaspoon contains 28 mg of decoquate.

#### Important:

Completely stir daily dose of **decoquate** powder into whole milk.  
Feed entire portion immediately.

#### Mixing Directions - Continuous Agitation

Mix Deccox-M into the total amount of whole milk (0.5 to 1.5 gallon per  
calf daily) needed for the number of calves to be fed. using level measuring  
cups, teaspoons (tsp) or tablespoons (TBS), as shown below. Prepare fresh daily.

If Average Calf Weight (lbs) is:	Amount of Deccox-M for				
	5 Calves	10 Calves	20 Calves	40 Calves	80 Calves
75	1 TBS	2 TBS	¼ cup	½ cup	1 cup
100	4 tsp	8 tsp	⅓ cup	⅔ cup	1 ⅓ cups
150	2 TBS	¼ cup	½ cup	1 cup	2 cups
200	8 tsp	⅓ cup	⅔ cup	1 ⅓ cups	2 ⅔ cups

Feed each calf an equal portion of the total amount of medicated  
whole milk prepared as above.

#### Important

Stir or agitate continuously.

Feed immediately in containers for individual animals only.  
Do not use in bulk feeding containers (i.e., Calf-Bars).

Failure to properly mix and feed this product may result in  
underdosing or overdosing of some animals due to settling  
out of the drug.

For Animal Use Only. Not for Use in Humans.  
Restricted Drug (CA). Use only as directed.

NADA 141-060, Approved by FDA.



Marketed by  
**ALPHARMA**  
Alpharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Net wt 10 LB (4.53 kg)

AHM-056 9807





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ALPHARMIA

# Deccox-M

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**LIBRARY**  
**540 EAST 57TH STREET**  
**CHICAGO, ILL. 60637**  
**TEL: 773-936-5000**  
**FAX: 773-936-5000**  
**WWW.CHICAGO.EDU**

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**Bag size: 16" x 4" x 34"**

## Decoquate Medicated Powder for Whole Milk

To be added to whole milk for the prevention of **coccidiosis** in ruminating and non-ruminating calves, including veal calves caused by *Eimeria bovis* and *E. zuernii*

Feed for at least **28 days** during periods of **coccidiosis** exposure or when experience indicates that **coccidiosis** is likely to be a hazard

Active ingredient Decoquate ..... (3632 mg/lb) 0.8%

Inactive ingredients Lactose ..... 87%  
Other (corn meal, soybean oil, lecithin and silicon dioxide) ..... 12.2%

### Directions for use Dosage:

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#### Mixing Directions - Individual Animal

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1 teaspoon per 120 lb body weight

1 ½ teaspoons per 180 lb body weight

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Marketed by  
**ALPHARMA**  
Alpharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Net wt 50 LB (22.67 kg)